EC Certificate
Full Quality Assurance System

Certificate No.:
13422-2018-CE-CZS-NA-PS Rev. 1.0

Project No.:
PRJC-575486-2017-PRC-CZE

Valid Until:
01 November 2023

This is to certify that the quality system of:

Biosintex S.R.L.
4 Vladiceasca Str.
077168 Snagov
Romania

For design, production and final product inspection/testing of:

Sterile surgical sutures

Has been assessed with respect to:

The conformity assessment procedure described in Annex II of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Digitally signed by Ceaicovschi Tudor
Date: 2020.11.20 15:41:24 EET
Reason: MoldSign Signature
Location: Moldova

Place and Date:
Høvik, 11 September 2019

For: DNV GL Presafe AS

Tone Kolpus

Tone Elise Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

NORWEGIAN ACCREDITATION

PROD 021
Notified Body No.: 2460

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Full Quality Assurance System

Certificate No.: **13422-2018-CE-CZS-NA-PS Rev 1.0**

Project No.: **PRJC-575486-2017-PRC-CZE**

Valid Until: **01 November 2023**

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
	Original Certificate	2018-11-01
1.0	**Change of product name**	**2019-09-11**

Products covered by this Certificate:

Product Description	Product Name	Class
Surgical suture with /without needle	**DACRIL**- Polyglycolic acid multifilament coated absorbable **DACRIL RAPID**- Polyglycolic acid multifilament coated fast absorbable **DACRIL 910** - Poly(glycolide-co-Lactide) (90/10) multifilament coated absorbable **PDO-x** - Polydioxanone monofilament absorbable **MONO-x** - Poly(glycolide-co-caprolactone) (75/25) monofilament absorbable **BIOPRO**- Polypropylene monofilament non-absorbable	III*

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 13464-2018-CE-CZS-NA-PS

Sites covered by this certificate

Site Name	Address
BIOSINTEX S.R.L.	4 Vladiceasca Str., RO 077168, Snagov, Romania

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
13422-2018-CE-CZS-NA-PS Rev 1.0	**PRJC-575486-2017-PRC-CZE**	**01 November 2023**

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

EC Design Examination Certificate

Certificate No.:
13464-2018-CE-CZS-NA-PS Rev. 1.0

Project No.:
PRJC-575486-2017-PRC-CZE

Valid Until:
01 November 2023

This is to certify that:

Sterile surgical sutures

Manufactured by:

Biosintex S.R.L.
4 Vladiceasca Str.
077168 Snagov
Romania

Has been assessed with respect to:

Examination of the design of the product as described in Annex II section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 11 September 2019

NORWEGIAN ACCREDITATION

PROD 021
Notified Body No.: 2460

For: DNV GL Presafe

Tone Kolpus

Tone Elise Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Design Examination Certificate

Certificate No.: **13464-2018-CE-CZS-NA-PS Rev. 1.0**

Project No.: **PRJC-575486-2017-PRC-CZE**

Valid Until: **01 November 2023**

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
	Original Certificate	2018-11-01
1.0	**Change of product name**	**2019-09-11**

Products covered by this Certificate:

Type of medical device and identification no.:	**Medical Device Class:**
Sterile surgical sutures	III

Short description of the Medical Device:

Surgical sutures with or without needle.

DACRIL - Polyglycolic acid multifilament coated, absorbable
DACRIL RAPID - Polyglycolic acid multifilament coated, fast absorbable
DACRIL 910 - Poly(glycolide-co-Lactide)(90/10) multifilament coated, absorbable
PDO-x- Polydioxanone monofilament, absorbable
MONO-x- Poly(glycolide-co-caprolactone) (75/25) monofilament, absorbable
BIOPRO- Polypropylene monofilament, non-absorbable

All the sutures are sterilized by Ethylene Oxide.

EC Design Examination Certificate

Certificate No.:	Project No.:	Valid Until:
13464-2018-CE-CZS-NA-PS Rev. 1.0	**PRJC-575486-2017-PRC-CZE**	**01 November 2023**

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall inform Presafe of any intended change of the products detailed above and Presafe will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

Conformity declaration and marking of product

This Certificate must be accompanied with a valid EC Certificate Full Quality Assurance System.

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

www.imq.it

CISQ is a member of

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N.
CERTIFICATE N. 9124.CRC4

SI CERTIFICA CHE IL SISTEMA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso medicale anche conto terzi. Produzione e stampa di etichette ad uso medicale. Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Sviluppo e produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori per uso medicale

Manufacture and print of special recording chart papers for medical use also on behalf of third parties. Manufacture and print of labels for medical use. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Development and manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories for medical use

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1999-07-20	2018-09-14	2020-10-07

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

Data di scadenza del precedente ciclo di certificazione: 2017-10-07
Data di conclusione dell'audit di rinnovo: 2017-10-11
Data della decisione di rinnovo: 2017-10-13

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

IMQ

Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

CSQ

www.imq.it

CISQ is a member of

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N. / *CERTIFICATE N.* 0967.2019

SI CERTIFICA CHE IL SISTEMA DI GESTIONE AMBIENTALE DI
WE HEREBY CERTIFY THAT THE ENVIRONMENTAL MANAGEMENT SYSTEM OPERATED BY

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

SITI / *SITES*

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 14001:2015

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi tramite processo di stampaggio. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radiofrequenza (RFID) tramite processo di stampaggio. Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche canto terzi tramite processo di miscelazione dei vari prodotti chimici ed imbottigliamento. Commercializzazione ed immissione in commercia di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Sviluppo e produzione di elettrodi per ECG tramite processi di accoppiamenti delle materie prime e taglio a misura. Gestione della produzione ed immissione in commercia di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties by molding process. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID) by molding process. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties by mixing various chemical products and bottling. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Development and manufacture of electrods for ECG through coupled processes of raw materials and cut to size. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters

Certificazione rilasciata in conformità al Regolamento Tecnico ACCREDIA RT-09

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2019-06-05	2019-06-05	2022-06-04

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

IMQ

FEDERAZIONE CISQ

www.cisq.com

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGA N° 006 D

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

IAF: 07, 09, 19, 12, 29

I processi riconducibili a settori IAF sottolineati risultano non ancora coperti da accreditamento
Processes related to underlined IAF sectors are not yet covered by accreditation

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

Organismo di Certificazione Federato CISQ
www.imq.it

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ *has issued an IQNet recognized certificate that the organization:*

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

has implemented and maintains a

Environmental Management System

for the following scope:

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties by molding process. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID) by molding process. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties by mixing various chemical products and bottling. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Development and manufacture of electrods for ECG through coupled processes of raw materials and cut to size. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters

which fulfills the requirements of the following standard:

ISO 14001:2015

Issued on: **2019 - 06 - 05**
Expires on: ***2022 - 06 - 04***

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: IT - 125879

Alex Stoichitoiu
President of IQNET

Ing. Claudio Provetti
President of CISQ

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE Turkey YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

CERTIFICATO CE

Certificato n. 1976/MDD

Dichiarazione di approvazione del sistema qualità

(Garanzia di qualità della produzione)

Visto l'esito delle verifiche condotte in conformità all'Allegato V, punto 3 e tenendo conto dell'Allegato VII, punto 5 della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

CERACARTA SPA

47122 FORLI' (FC) - VIA SECONDO CASADEI 14 Z.I. VILLA SELVA (ITA) - Italy

mantiene negli stabilimenti di:

47122 FORLI' (FC) - VIA SECONDO CASADEI 14 Z.I. VILLA SELVA (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Carte per registrazione ad uso medico

Modd. come da documento allegato "ELENCO CARTE DIAGRAMMATE CLASSE I F.M. REV.15 - 16/10/2017"; valido solo se provvisto di timbro IMQ.
Marca Ceracarta

ai requisiti metrologici ad essi applicabili della direttiva suddetta (in tutte le fasi della fabbricazione) ed è sottoposta alla sorveglianza prevista dal punto 4 dell'Allegato V.

Riferimento pratiche IMQ:
DM17-0017248-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i.
Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il: 2017-11-18

Data Scadenza: 2022-11-17

IMQ

cosign

IMQ CSQ
ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

Questa Dichiarazione di approvazione è soggetta alle condizioni previste dall'IMQ nel "Regolamento per la certificazione CE dei dispositivi medici in base alla direttiva 93/42/CEE".

EC CERTIFICATE

Certificate No 1976/MDD

Production Quality Assurance System Approval Certificate

On the basis of our assessment carried out according to Annex V, section 3 and considering the Annex VII, section 5 of the Directive 93/42/EEC and its revised version, we hereby certify that:

CERACARTA SPA

47122 FORLI' (FC) - VIA SECONDO CASADEI 14 Z.I. VILLA SELVA (ITA) - Italy

manages in the factories of:

47122 FORLI' (FC) - VIA SECONDO CASADEI 14 Z.I. VILLA SELVA (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Electromedical recording chart paper

Type ref. as to annexed document "ELENCO CARTE DIAGRAMMATE CLASSE I F.M. REV.15 - 16/10/2017"; valid only if provided with IMQ stamp.
Trade mark Ceracarta

with the relevant metrological requirements of the aforementioned directive (as far as all the manufacturing stage is concerned) and it is subject to surveillance as specified in section 4 of Annex V.

Reference to IMQ files Nos:
DM17-0017248-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version.
Notified Body notified to European Commission under number: 0051.

Date: 2017-11-18

Expiry Date: 2022-11-17

IMQ

cosign

IMQ CSQ
ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".

This is a translation of the Italian text, which prevails in case of doubts

CERACARTA® S.p.A.

Carte diagrammate per tutte le apparecchiature di elettrodiagnostica.
Materiale di consumo ed accessori elettromedicali.
Carte per apparecchi registratori industriali.
Rotoli e pacchi speciali per sistemi esattoriali, di controllo, lotterie.
Etichette radiofrequenza e soluzioni integrate.

Chart Papers for all electrodiagnostic equipment
Disposable and electromedical accessories.
Chart Papers industrial recording instruments.
Special rolls and fanfolds for tickets checking sys
lottery.
Rfid labels and chain solutions.

Sede (Head office and works) :
Via Secondo Casadei, 14 - 47122 FORLI' – ITALY
Tel : 0039 0543 780055 • Fax : 0039 0543 781404
http : // www.ceracarta.it • e-mail : info@ceracarta.it.
Capitale Sociale : € 1.000.000 int. vers.
Registro Imprese FORLI'-CESENA
P.I. / C.F. / VAT.N. IT 00136740404
R.E.A. FORLI' N. 72646 – N. MECC. FO 006863

ELENCO CARTE DIAGRAMMATE CLASSE I F.M. REV.15 - 16/10/2017

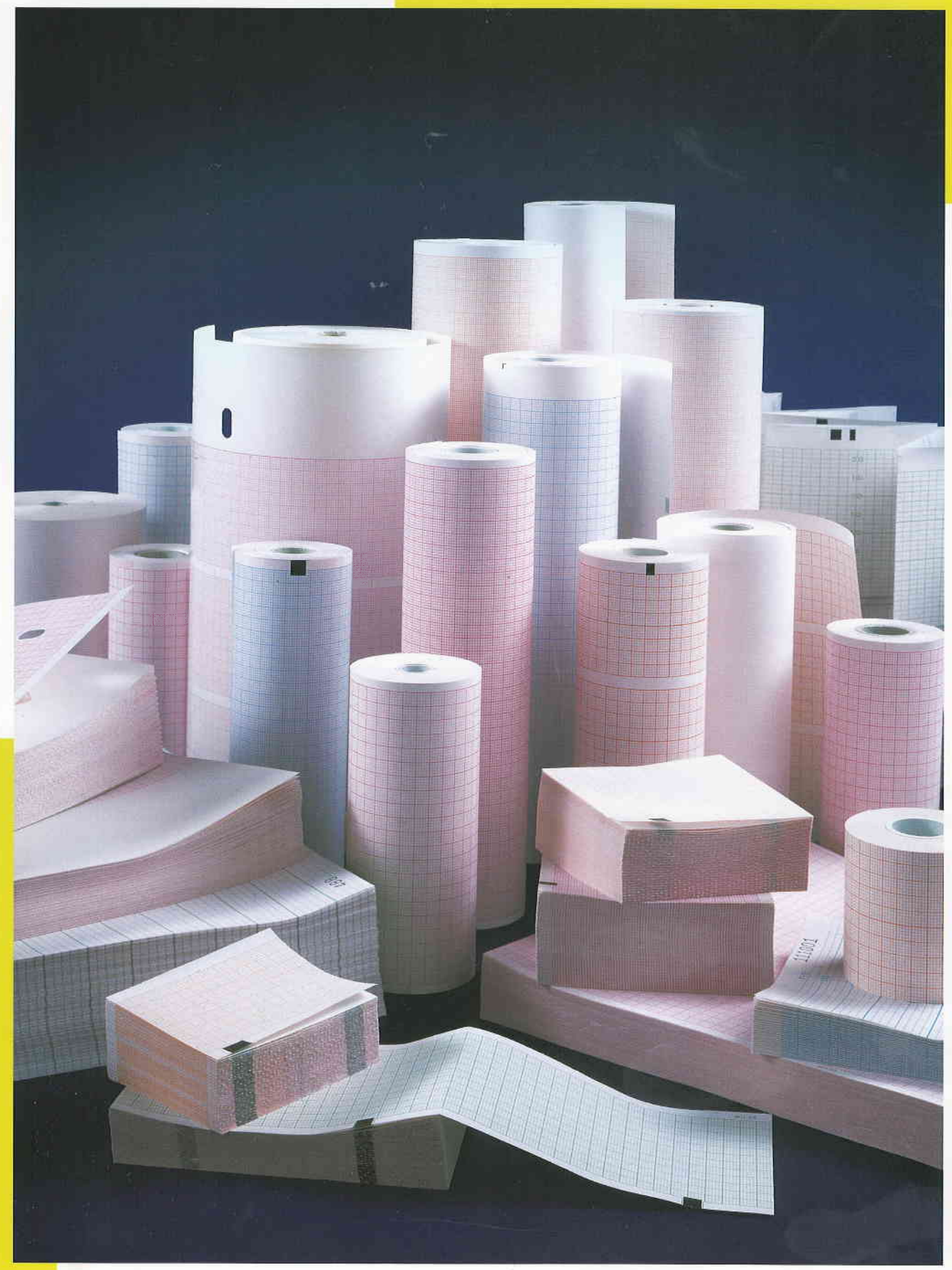
Codice famiglia identificativo	Descrizione famiglia
22.01	Pacchi stampati medicali (per ECG,EEG,CTG,e laboratorio analisi)
21.01	Rotoli stampati medicali (per ECG,EEG,CTG,e laboratorio analisi)
32.01	Schede e dischi stampati medicali

2017-11-18

CHART PAPERS

ceracarta

CHART PAPER



Widest choice of articles for a variety of sectors including: - ELECTROCARDIOGRAMS - ELECTROENCEPHALOGRAMS - FOETAL MONITORING - NEUROLOGY - GYNAECOLOGY - PNEUMOLOGY - INTENSIVE CARE UNITS - POLIGRAPHS - RESUSCITATION - ULTRASOUND SCANS - LABORATORY ANALYSES

If requesting an offer, please state: model and instrument code, where possible the paper code and, in any case, the sizes. For eeg z-folds colour and line distance.

PAPERS FOR ECG

From the simplest single-channel instruments to the most complex appliances for stress tests or for particular monitoring of coronary units, the best solution for all quality and operation requirements can be found in the articles produced by Ceracarta. Research and study of the best support for each specific appliance derives from an in-depth knowledge of the instruments on which various types of paper are used.

Furthermore constant checks, detailed control and regular technological updating ensure continuously high efficiency in recording. For particular requirements we can supply paper which guarantees conservation of the recording trace for more than 20 years. Ceracarta always guarantees the absolute reliability of its paper with respect to all the instruments available commercially, even the less common.

PAPERS FOR EEG

In view of the particular nature of EEG instruments and the diversity of their functions, paper manufacturers must be extremely careful when evaluating the various characteristics of the appliance and be very flexible in varying basic raw materials.

A great priority must be given to the perfect running of the paper and to its excellent recepitivity as for the writing pen. Through its paper Ceracarta constantly guarantees best results also in this sector, even during long recordings, thanks to its perfect adaptability, specifically and attentively researched, for all types of instruments.

PAPERS FOR CTG

The extremely precise printing of diagrams and base scales and the gauged sensitivity of thermal paper are essential for the best functioning of the foetal monitoring equipment and, therefore, an excellent diagnostic reading.

Ceracarta has paid special attention to these details, manufacturing products which, also due to the perfection of the lateral holes and the numbering of each page, and owing to the accuracy of the regulating sensors, are among the best available commercially, where too often paper of insufficient efficiency is on offer. Ceracarta represents a guarantee, not found everywhere, also in the sector of foetal monitoring.

PAPERS FOR ANALYSIS LABORATORY AND LABELS

The apparent simplicity of papers for instruments of analysis has often induced consumers to be easily satisfied to the detriment of the quality of the report and, especially of the conservation over time of documentation relating to the analysis.

Also in this field, specialisation is crucial and the quality of the raw materials used is of a primary importance. Ceracarta is at your disposal with rolls and packs for all types of instruments used in laboratories, guaranteeing optimal functioning and a perfect result.

Ceracarta produces thermal paper labels, papers for thermal transfer printers and polyester films for analysis laboratories and transfusion centres, manufactured with special materials and adhesives, for all requirements.

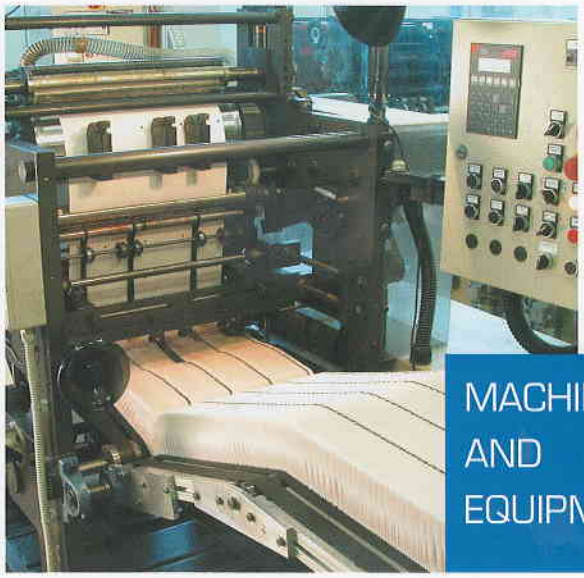
Whatever the use (labels for test tubes, medical reports, radiological envelopes or " blood bags"), an excellent outcome is ensured. Ceracarta has implemented a division for the production of labels and tickets with a microchip (RFID technology) to be applied also to the medical field.

CHART PAPER

THE COMPANY CERACARTA

- We are leaders in Europe for the manufacturing of paper for electrical diagnostic instruments and industrial recording with more than 40 years' experience in the medical sector.
- Advanced technologies, equipment and methodical quality controls for the production of specific chart and non-chart paper for all diagnostic equipment available on the international market.
- Superior quality materials and absolute manufacturing precision for perfect diagnosis.
- Study and research centre to meet any specific need or customisation requirement and client consulting service.
- Documents and samples sent on request.
- ISO 9002 - EC certification - 2000 vision / ISO46002 / 93-42-CE

THE WAREHOUSE



MACHINES AND EQUIPMENT

WAREHOUSE

Perfect service offered to customers in terms of guaranteeing delivery times, the great care paid when choosing the most suitable form of packaging for the type of shipment, as well as the perfect correspondence between the product supplied and what is requested. • Optimal management of the stock related to production programmes: all this is guaranteed by a computerised system which now supports the traditional bar code, the revolutionary and brand-new radio frequency transponder system (TAG). • Professional skill and competence of our staff ensure an ideal service for customers.

MACHINES AND EQUIPMENT

After the new premises were set up, the machinery has been almost completely replaced or modified in order to improve the quality of the product even further, while at the same time speeding up production times which means lower costs for the customer.The whole production system has the advantage of a double check: from the specialised technical staff and the automated computer control.

CE
Products EC compliants

CERACARTA

COMPANY
WITH QUALITY SYSTEM
CERTIFIED BY DNV
ISO 9000

Via Secondo Casadei N.14
zona industriale Villa Selva - 47100 Forlì (Italy) tel. +39.0543.780055 - fax +39.0543.781404
www.ceracarta.it - e mail: info@ceracarta.it

CERTIFICATE

No. 490115

LL-C Certification

This is to certify that the Quality Management System of Medical Devices of

KIRCHNER & WILHELM GmbH + Co. KG
Eberhardstr. 56
71679 Asperg
Germany

has been assessed and found to be in compliance with the standard

ISO 13485:2016

applicable to

Development, production and sales of medical devices for general medicine, otolaryngology, ophthalmology, anesthesiology and dermatology.

The certificate has been issued under No. **490115** for the registration period from 16th February 2018 to 15th February 2021.

Approved by

Printed by

S 3137

validity code: **8EEAA4C4-DD7**
Check the validity of this certificate using this code at **www.ll-c.info**

DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Certificate No:
276614-2018-AQ-ROU-RvA

Initial certification date:
17 April 2008

Valid:
16 November 2019 - 15 November 2022

This is to certify that the management system of

BIOSINTEX S.R.L.

4 Vladiceasca Str.,RO 077168, Snagov, Ilfov County, Romania

has been found to conform to the Quality Management System standard:
ISO 9001:2015

This certificate is valid for the following scope:
Design, development, manufacturing and trade of sterile surgical sutures, with/ without needles, surgical sterile prosthesis for soft tissues and surgical meshes for women urinary incontinence.

Place and date:
Bucharest, 07 November 2019

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT
IAF
MGMT. SYS.
RvA C 024

The RvA is a signatory to the IAF MLA

For the issuing office:
DNV GL – Business Assurance
61 Tunari, 2nd district, RO-020561,
Bucharest, Romania

Daniel Savu
Management Representative

СИСТЕМА СЕРТИФИКАЦИИ ГОСТ Р

ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

Добровольная сертификация

СЕРТИФИКАТ СООТВЕТСТВИЯ

№ РОСС RU.AM05.H01992

Срок действия с 13.06.2019 **по** 12.06.2022

№ 0474991

ОРГАН ПО СЕРТИФИКАЦИИ RA.RU.11AM05

Орган по сертификации продукции ООО "Центр сертификации и экспертизы "Тверьэкс". Адрес: 141006, РОССИЯ, Московская область, г. Мытищи, пр-т Олимпийский, владение 43, стр. 1. Телефон +7-925-636-1225, адрес электронной почты: os-tverex@yandex.ru

ПРОДУКЦИЯ Материал упаковочный для стерилизации: пакеты и рулоны для стерилизации с использованием паров перекиси водорода «СтериТ®» ТУ 9398-095-11764404-2012. Приложение бланк №0072675, 0072676. Серийный выпуск.

код ОК
32.50.50.190

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ НОРМАТИВНЫХ ДОКУМЕНТОВ

ГОСТ ISO 11607-1-2018,
ГОСТ Р 50444-92

код ТН ВЭД
3822 00 000 0

ИЗГОТОВИТЕЛЬ Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР». ОГРН: 1027739440860, ИНН: 5023001024, КПП: 770101001. Адрес: Место производства: 152020,, РОССИЯ, Ярославская обл., г. Переславль -Залесский, ул. Большая Протечная, д. 51б, телефон/факс: +7 (495) 988-76-67, адрес электронной почты: vinar@vinar.ru.

СЕРТИФИКАТ ВЫДАН Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР». ОГРН: 1027739440860, ИНН: 5023001024, КПП: 770101001. Адрес: 105094, РОССИЯ, г. Москва, Госпитальный вал, д. 5, стр. 7А, пом. VIII, телефон/факс: +7 (495) 988-76-67, адрес электронной почты: vinar@vinar.ru.

НА ОСНОВАНИИ Протокол испытаний № 00202-РПП/ЦСМК/2019 от 11.06.2019 г. выдан испытательной лабораторией Общество с Ограниченной Ответственностью "ЦСМК", свидетельство о подтверждении компетентности испытательной лаборатории № РОСС.RU.31801.RU.ИЦ012 от 12.03.2019.
Регистрационное удостоверение № РЗН 2013/17 от 04.04.2016г. Федеральной службы по надзору в сфере здравоохранения (РОСЗДРАВНАДЗОР).

ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ

Схема сертификации: 3

Для сертификатов

М.П.

Руководитель органа _____ А.А. Белянин
подпись — инициалы, фамилия

Эксперт _____ А.Ю. Батюков
подпись — инициалы, фамилия

Сертификат не применяется при обязательной сертификации

АО «ОПЦИОН», Москва, 2018, «В» лицензия № 05-05-09/003 ФНС РФ, тел. (495) 726 4742, www.opcion.ru

СИСТЕМА СЕРТИФИКАЦИИ ГОСТ Р

ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

№ 0072675

ПРИЛОЖЕНИЕ

К сертификату соответствия № РОСС RU.AM05.H01992

Перечень конкретной продукции, на которую распространяется действие сертификата соответствия

код ОК код ТН ВЭД	Наименование и обозначение продукции, ее изготовитель	Обозначение документации, по которой выпускается продукция
32.50.50.190	Материал упаковочный для стерилизации: пакеты и рулоны для стерилизации с использованием паров перекиси водорода «СтериТ®»:	ТУ 9398-095-11764404-2012
	1. Пакеты самоклеящиеся для стерилизации с использованием паров перекиси водорода «СтериТ®»: Ширина пакета, мм - 30-800, Длина пакета, мм - 40-1000, Ширина бокового шва, мм - 6-15.	
	2. Пакеты плоские для стерилизации с использованием паров перекиси водорода «СтериТ®»: Ширина пакета, мм - 30-800, Длина пакета, мм - 40-1000, Ширина бокового шва, мм - 6-15.	
	3. Пакеты со складками для стерилизации с использованием паров перекиси водорода «СтериТ®»: Ширина пакета, мм - 30-800, Длина пакета, мм - 40-1000, Ширина складки, мм - 15-200, Ширина бокового шва, мм - 6-15.	
	4. Рулоны плоские для стерилизации с использованием паров перекиси водорода «СтериТ®»: Ширина рулона, мм - 30-800, Длина рулона, м - 20-500, Ширина бокового шва, мм - 6-15.	

Руководитель органа _____ А.А. Белянин
подпись — инициалы, фамилия

Эксперт _____ А.Ю. Батюков
подпись — инициалы, фамилия

Центр сертификации и экспертизы «Тверьстандарт» аттестат аккредитации № RA.RU.11АМ05 Для сертификатов ООО

АО «ОПЦИОН», Москва, 2018, «В» лицензия № 05-05-09/003 ФНС РФ, тел. (495) 726 4742, www.opcion.ru

СИСТЕМА СЕРТИФИКАЦИИ ГОСТ Р

ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

№ 0072676

ПРИЛОЖЕНИЕ

К сертификату соответствия № РОСС RU.AM05.H01992

Перечень конкретной продукции, на которую распространяется действие сертификата соответствия

код ОК код ТН ВЭД	Наименование и обозначение продукции, ее изготовитель	Обозначение документации, по которой выпускается продукция
	5. Рулоны со складками для стерилизации с использованием паров перекиси водорода «СтериТ®»: Ширина рулона, мм - 30-800, Длина рулона, м - 20-500, Ширина складки, мм - 15-200, Ширина бокового шва, мм - 6-15.	

Руководитель органа _____ А.А. Белянин
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М.П.

Эксперт _____ А.Ю. Батюков
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